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10/524,394

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Carl Gustav Figdor

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ROPES & GRAY LLP

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LI, RUXIANG

ART UNIT

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1646

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/524,394

## Applicant(s)

FIGDOR ET AL.

## Examiner

RUIXIANG LI

## Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-850)  
Paper No(s)/Mail Date 05/11/2005, 05/13/2008
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-13, drawn to a method of treating a person with rheumatoid arthritis, comprising administering to said person an effective amount of a compound that blocks an interaction between DC-SIGN and ICAM-3.
  - II. Claims 14-18, drawn to a method to diagnose whether a human has rheumatoid arthritis, comprising measuring the percentage of inflammatory cells that express DC-SIGN from synovia of said human.
  - III. Claims 19-25, drawn to a method to isolate macrophages from other cells in a biological sample, comprising a) contacting said sample with an agent that binds DC-SIGN and b) separating cells that bind to said agent from cells that do not bind to said agent.
2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is considered to be a method of treating a person with rheumatoid arthritis, comprising administering to said person an effective amount of a compound that blocks an interaction between DC-SIGN and ICAM-3.

The special technical feature of Group II is considered to be a method to diagnose whether a human has rheumatoid arthritis, comprising measuring the percentage of inflammatory cells that express DC-SIGN from synovia of said human.

The special technical feature of Group III is considered to a method to isolate macrophages from other cells in a biological sample, comprising a) contacting said sample with an agent that binds DC-SIGN and b) separating cells that bind to said agent from cells that do not bind to said agent.

Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

3. During a telephone conversation with Jennifer Holmes on September 4, 2008 a provisional election was made without traverse to prosecute the invention of Group III, Claims 19-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

4. The information disclosure statements filed on 05/13/2008 and 05/11/2005 have been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action.

***Drawings***

5. The drawings filed on 02/10/2005 are accepted by the Examiner.

***Objection to Title***

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

***Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 19-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 19-25 are drawn to a method to isolate macrophages from other cells in a biological sample, said method comprising a) contacting said sample with an agent that binds DC-SIGN and b) separating cells that bind to said agent from cells that do not bind to said agent. The claims are broad because they encompass a method to isolate macrophages from other cells in a biological sample using any agents that bind DC-SIGN.

The specification discloses that DC-SIGN, an ICAM-3 binding C-type lectin, is extensively expressed on both CD68 expressing tissue macrophages and dendritic cells present in the synovium of RA patients (page 6, paragraph [0024]; page 9, paragraph [0044])). The prior art also teaches that DC-SIGN is expressed in dendritic cells in tissues of healthy donors, which is acknowledged by the applicants (page 4, paragraph [0011]). Thus, an agent that binds DC-SIGN will bind to both macrophages and dendritic cells. Such an agent cannot be used in the claimed method to separate

macrophages from dendritic cells.

Moreover, claim 19 recites a broad genus of agents that bind DC-SIGN, whereas claim 22 recite a mannose carbohydrate, a fucose carbohydrate, a plant lectin, an antibiotic, a sugar and a protein. The specification teaches agents that bind DC-SIGN: plant lectins, such as concanavalin A, antibiotics, a such as pradimicin, sugars such as N-acetyl-D-glucosamine and galactose (page 10, paragraph [0050]). However, neither the specification nor the prior art teaches any plant lectins, antibiotics, or any sugars bind to DC-SIGN.

Accordingly, the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

#### ***Claim Objection—Informality***

9. Claim 22 is objected to because it recites a mannose carbohydrate, a fucose carbohydrate and a sugar, whereas sugar (the genus) encompasses a mannose carbohydrate and a fucose carbohydrate (species). Appropriate correction is required.

#### ***Conclusion***

10. No claims are allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/  
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.  
September 11, 2008